

K 043429

JAN 12 2005

510(K) Summary

Submitter: Cynosure, Inc.
10 Elizabeth Drive
Chelmsford, MA 01824

Contact: George Cho
Senior Vice President of Medical Technology

Date Summary Prepared: December 9, 2004

Device Trade Name: Cynergy Laser

Common Name: Medical Laser System

Classification Name: Instrument, surgical, powered, laser
79-GEX
21 CFR 878.48

Equivalent Device: Cynosure TriStar laser

Device Description: The Cynergy is a user selectable, multi wavelength laser, having both an organic dye and an Nd:YAG rod lasing medium. It is a pulsed dye laser with wavelengths of 585, 590, 595, 600nm and an Nd:YAG laser with a wavelength of 1,064nm.

Laser activation is by footswitch. Overall weight of the laser is 285lbs, and the size is 41"x18"x32" (HxWxD).

Electrical requirement is 110 VAC or 220 VAC, 20A, 50-60 Hz, single phase.

Intended Use: The Cynergy is indicated for treatment of vascular lesions, pigmented lesions, tattoos, wrinkles and hair removal.

Comparison: The Cynergy laser is substantially equivalent to the TriStar laser, with the same indications for uses, the same principle of operation, and similar wavelengths and fluence range as the predicate devices.

Nonclinical Performance Data: none

Clinical Performance Data: none

Conclusion: The Cynergy laser is another safe and effective device for treating vascular lesions, pigmented lesions, tattoos, wrinkles and hair removal

Additional Information: none



JAN 12 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. George Cho
Senior Vice President of Medical Technology
Cynosure, Inc.
10 Elizabeth Drive
Chelmsford, Massachusetts 01824

Re: K043429
Trade/Device Name: Cynergy Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and
plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: December 9, 2004
Received: December 13, 2004

Dear Mr. Cho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K 043429

Device Name: Cynosure Cynergy Laser

Indications For Use:

585 – 600nm: The Cynergy laser is indicated for benign vascular and vascular dependant lesions removal.

1,064nm: The Cynergy laser is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lakes, leg veins, spider veins, and poikiloderma of civatte and treatment of benign cutaneous lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots), café au lait manules, seborrheic keratoses, nevi, chloasma, verrucea, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos) and plaques.

The laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.

Additionally, the laser is intended for the removal of unwanted hair, for the stable long term, or permanent, hair reduction through selective targeting of melanin in hair follicles, and for the treatment of psuedofolliculitis barbae (PFB).

Prescriptive Use X OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

510(k) Number K043429